K001651

NOV 2 2 2000

NOT CONFIDENTIAL

"Special" 510(k) Summary

The Bio-Rad %CDT TIA is an *in vitro* reagent system for the quantitative measurement of carbohydrate-deficient transferrin in human serum. Bio-Rad %CDT TIA measures the relative amount of carbohydrate-deficient transferrin in proportion to total transferrin.

The %CDT TIA can be used as a tool to identify a possible chronic heavy alcohol consumption.

Serum transferrin is a glycoprotein with a molecular weight of about 80kD, which comprises a single polypeptide chain with two N-linked polysaccharide chains. These polysaccharide chains are branched with terminal sialic acid residues. Human transferrin occurs in isoforms with different levels of sialylation. There appear to be at least six such isoforms, from penta to asialo transferrin.

Daily intake of alcohol exceeding 60 grams of ethanol for periods longer than two weeks may result in elevated levels of CDT.

The Bio-Rad %CDT TIA is a heterogeneous immunoassay with column separation followed by turbidimetric measurement. Serum transferrin in the sample is saturated with Fe^{3+}. The mixture is applied to an ion-exchange column. Due to the different amounts of sialic residues on transferrin, the isoforms carry different charges and are separated in the column. The CDT isoforms are eluted. The CDT content of the collected eluate is determined by turbidimetric measurement.

The eluted CDT isoforms form immune complexes with anti-transferrin antibodies. Total transferrin content of the sample is determined separately, using the same anti- transferrin antibodies. The measurements are evaluated using a calibration curve, and the %CDT value is calculated.

Bio-Rad %CDT TIA was compared to Axis® %CDT TIA in the study CT-C9003 and safety and efficacy of the Bio-Rad %CDT TIA was determined.

The issues addressed in this study were clinical distribution of Bio-Rad %CDT TIA in social drinkers and in chronic heavy drinkers, the comparison between Bio-Rad %CDT TIA and Axis® %CDT TIA, the sensitivity and specificity of Bio-Rad %CDT TIA at various cut-off levels, and the performance of Bio-Rad %CDT TIA in a US laboratory.

The study demonstrated that chronically heavy drinking individuals have higher CDT levels than socially drinking individuals, and that females and males do not have substantially different %CDT levels which suggests that a common cut-off

could be utilized for males and females. The correlation between Bio-Rad %CDT TIA and Axis® %CDT TIA was high (0.80). Sensitivity and specificity of Bio-Rad %CDT TIA at a reference value of 2.6 %CDT was 0.73 and 0.96 for males and 0.52 and 0.94 for females respectively. 2.6 % is identical to the 95 % percentile value observed in the social drinking (normal population) group. Among social drinkers, females have slightly higher %CDT levels than males. Visual inspection of ROC curves comparing Bio-Rad %CDT TIA and Axis® %CDT suggests that there is no difference in the performance characteristics for the two tests, which was further confirmed by very small differences in the areas under the curves for both tests.

Design control activities have included risk analysis, verification, validation and recording, and are declared to conformity with design control.

Conclusion

When considering the above noted comparison between Bio-Rad %CDT TIA and Axis® %CDT TIA, (the predicted device) and with reference to the documented comparison of Bio-Rad %CDT TIA to Axis® %CDT TIA (see section Comparison to Predicated Device), it can be concluded that the Bio-Rad %CDT TIA is substantially equivalent to Axis® %CDT TIA.

Ronald G. Leonardi, Ph.D.

May 26, 2000

Abbreviations

CDG-syndrome - Carbohydrate deficient glyco-protein syndrome
CDT - Carbohydrate Deficient Transferrin
CV - coefficient of Variance
GGT - Gamma Glutamyl Transferase
HPLC - High Performance Liquid Chromatography
kD - kilo Dalton
LOD - Limit of Detection
LOQ - Limit of Quantification
N/A - not applicable
P&U - Pharmacia & UpJohn
PI - Package Insert
SD - Standard Deviation
TIA - Turbidimetric Immunoassay
TT - Total transferrin
US - United States

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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NOV 22 2000

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c/o Ronald G. Leonardi, Ph.D.
R & R Registrations
P.O. Box 262069
San Diego, California 92196-2069

Re: K001651
Trade Name: Bio-Rad %CDT TIA
Regulatory Class: I reserved
Product Code: NAO, JJX
Regulatory Class: II
Product Code: JIS
Dated: October 17, 2000
Received: October 18, 2000

Dear Dr. Leonardi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) : K001651

Device Name: BioRad %CDT TIA

Indications for Use:

The %CDT TIA is an *in vitro* reagent system for the quantitative measurement of carbohydrate-deficient transferrin in human ~~serum~~. %CDT TIA measures the relative amount of carbohydrate-deficient transferrin in proportion to total transferrin.

The %CDT TIA can be used as a tool to identify a possible chronic heavy alcohol consumption.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001651

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)